

Amendments to the Drawings:

Please refer to Drawing Replacement Sheets submitted with this paper.

Amendments to the specification:

In the title, please amend as follows:

Method and Apparatus for Treating Obstructive Sleep Apnea Syndrome

Replace the section entitled “Description of Figures” appearing on page 12 of the specification with the following:

Description of Figures Brief Description of the Drawings

Figure 1 shows the present invention utilizing a single-piece, dual arch, obturator with an acrylically-connected slide upon which moves an adjustable PAP Tubing Retention Platform device.

Figure 2a shows the PAP Tubing Retention Platforms in variable adjacent to a small widths (small, medium, and large) corresponding with variable nare and nasal widths.

Figure 2b shows the PAP Tubing Retention Platform adjacent to a medium nare and nasal width.

Figure 2c shows the PAP Tubing Retention Platform adjacent to a large nare and nasal width.

Figure 3 shows a superior view of the dual arch, obturating airway orthotic with anterior supported for an array of varying width PAP Tubing Retention Platforms. Only one size PAP Tubing Retention Platform is shown in this figure.

Figure 3a is a top view of the PAP Tubing Retention Platform.

Replace the section entitled “Description of the Preferred Embodiment” beginning on page 12 and ending on page 15 of the specification with the following:

Detailed Description of the Preferred Embodiment

Figure 1 shows a lateral view of the present invention. This view is from the patient's right side where the Upper Right Quadrant [1] is superior and the Lower Right Quadrant [2] is inferior. Posteriorly there is Tongue Space A [3] just where the Solid Acrylic Obturating Seal [8] ends. Typically the Solid Acrylic seal will extend to at least the mesial aspect of the maxillary first molar if not slightly further to create the most robust seal. The Upper Dental Arch [5] is superior to the Lower Dental Arch [6]. The airway orthotic is composed of Exterior Hard Acrylic [7] and is lined interiorly with Elastomeric Material [4]. Anteriorly the 5mm Slide Mount [16] is operatively connected to the Variable Length Slide [13]. Upon the Variable Length Slide the Variable Width PAP Tubing Retention Platform [12] is adjustably affixed to the Variable Length Slide via the Slide Mount Bracket [14]. Superiorly and anteriorly there is a Nasal Pillow [9] which fits over a Collar [10]. The Collar inserts into the PAP Tubing [15] which is threaded through the Variable Width PAP Tubing Retention Platform via the PAP Tubing Hole (Figure 3, [18]). At a certain preferred distance from the nose inferiorly is a Whisper Swivel II Valve (Respironics Part Number 332113). Above the Whisper Swivel II Valve and within the PAP Tubing is located an optional Exhaust Port [11]. Both the Whisper Swivel II Valve and the Exhaust Port are utilized to blow off or vent Carbon Dioxide (CO₂) on patient exhalation. The rate of expiratory flow from use of these structures is between 5-15 liters per minute. The need for the optional Exhaust Port can be determined in the sleep laboratory by end tidal CO₂ monitoring. If the patient is retaining too much CO₂ PAP Tubing Holes are created to assist the Whisper Swivel II Valve in blowing off excess CO₂.

Figure 2 shows the Present Invention whereby a method of treating Obstructive Sleep Apnea Syndrome utilizes PAP Tubing Retention Platforms that are variable in widths to correspond with variations in nasal and nare width. Figure 2 shows three hypothetical patient nasal widths small, medium, and large that correspond with particular width PAP Tubing Retention Platforms (small [12a], medium [12b], and large [12c]). The reader will note that there could be additional Platforms as necessary to accommodate any and all variations in patient nasal widths. If there is flaring of the nares superiorly the PAP Tubing Retention Platforms may be increased slightly in width to allow for angulation medially of the Platform via application of heat to bend the acrylic so as to customize the angular approach of the PAP Tubing [15]. The preferred thickness of the Variable Width PAP Tubing Retention Platforms should be at least 3mm. These PAP Tubing Retention Platforms can be manufactured via standard methods such as heat “suck-down” whereby a 3mm sheet of acrylic such as Biocryl is heated until pliable and vacuum-formed onto various width molds forming the preferred structures. They may also be injection molded or cast directly in acrylic via the lost wax technique. The PAP Tubing Retention Platform is mounted onto the Slide [13] via the Slide Mount (Figure 1) and can be preferably located or adjusted as close as 5mm from the labial surface of the anterior teeth. The preferred range of location of the PAP Tubing [15] will be 5mm to 30mm from the labial surface of the maxillary anterior teeth. Once the preferred location antero-posteriorly is located for the individual patient the Slide [13] may be cut to reduce unnecessary lever arm forces.

Figure 3 shows the present invention in a superior view and Figure 3a is a top view of the PAP Tubing Retention Platform 12. The Variable Width PAP Tubing Retention Platform [12] is shown in two widths and styles in this figure and is mounted onto the Variable Length Slide [13] via the Slide Mount Bracket [14]. The first style is rectangular and the second style is “U” shaped. There are two PAP Tubing Holes [18] which correspond to the right and left nares in both styles. The width of the PAP Tubing Retention Platform and position of the holes is preferably selected to match the corresponding width of the patient’s nasal and nare width. The Solid Acrylic Obturating Seal [8] continues from the anterior region of the airway orthotic posteriorly as

necessary to seal off the oral cavity from loss of requisite therapeutic positive airway pressure as determined in the sleep laboratory. There is Tongue Space A anteriorly, laterally, and vertically. The vertical or caudal dimension of the airway orthotic is varied according to tongue size and is determined by the experienced clinician through a variety of means or methods. The preferred embodiment utilizes a neuromuscular TENS (Transcutaneous Electrical Nerve Stimulation) technique whereby the masticatory muscles are profoundly relaxed to proper working lengths via this pulsing technique placing the mandible in three dimensional harmonious space position with respect to the maxilla. In this manner the mandibular position antero-posteriorly (AP) and vertically is determined by the muscles themselves rather setting an arbitrary position. This neuromuscularly-determined position is referred to earlier in the specification as "neutral centric" position. If the need presents, due to excessive therapeutic PAP requirements for an individual patient, the AP position of the mandible may be somewhat protruded forward so as to create some mechanical dilation of the upper airway. However, this forward positioning of the mandible will increase the risk of a deleterious change in the patient's occlusion or bite. Therefore, the preferred position will typically be the neutral centric position as determined by the experienced clinician.

The foregoing description of the preferred embodiments of the invention has been presented for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Accordingly, the foregoing description should be regarded as illustrative rather than restrictive, and it should be appreciated that variations may be made in the embodiments described by workers skilled in the art without departing from the scope of the present invention as defined by the following claims.

What is claimed is: